



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2015

Philips Consumer Lifestyle
Marta Walker
Sr. Safety, Compliance & Regulatory Manager
1600 Summer Street
Stamford, Connecticut 06905

Re: K151033
Trade/Device Name: Philips Self-adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 7, 2015
Received: April 17, 2015

Dear Marta Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

Device Name
Philips Self-Adhesive Electrodes

Indications for Use (Describe)

The Philips Self-Adhesive Electrodes are intended for use with the PulseRelief device for applying Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscle Stimulation (EMS)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by section 21 CFR 807.92

1. SUBMITTER OF 510(K):

Company name: Philips Consumer Lifestyle
Registration number: 3009181561
Address: 1600 Summer Street
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email: marta.walker@philips.com
Correspondent: Marta Walker,
Sr. Safety, Compliance & Regulatory

Date of Preparation: July 21st , 2015

2. DEVICE:

Trade/Proprietary Name: Philips Self-Adhesive Electrodes
Common/Usual Name: Electrodes
Regulation Name: Electrodes, Cutaneous
Classification Name: Neurological Diagnostic Devices
Classification: 21CFR 882.1320 Class II
Product Code: GXY

3. PREDICATE DEVICE

Our new device is based on the legally marketed device cited in the table below:

Table 1: Predicate device

Manufacturer	Device	510(k) #
Axelgaard Manufacturing Co. LTD, 520 Industrial Way, Fallbrook, CA 92028	ValuTrode® Neurostimulation Electrodes	K130987

4. DEVICE DESCRIPTION

The Philips Self-Adhesive Electrodes is used as a transcutaneous electrical nerve stimulation electrode in conjunction with the Philips PulseRelief device which is an electrical stimulator for TENS or EMS.

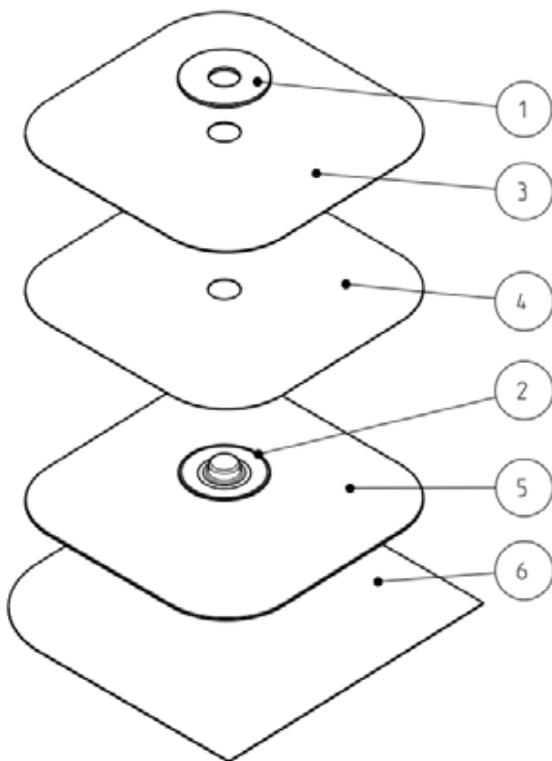
Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

4.1 Technical characteristics

It is composed of :

1. Metal target
2. Rivet
3. Textile adhesive layer
4. Carbon layer
5. Hydrogel layer
6. Backing sheet

See picture below:



Proper current distribution is delivered via use of a printed silver pattern.

Axelgaard manufactures both the Philips Self-Adhesive Electrodes and the predicate electrodes K130987, with the same conductive hydrogel (tested for biocompatibility), conductive carbon film, printed silver pattern and electrode carrier liner

5. INDICATION FOR USE

The Philips Self-Adhesive Electrodes are intended for use with the PulseRelief device for applying Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscle Stimulation (EMS).

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2: Substantial Equivalence Comparison Table

Topic	Self-Adhesive Electrodes	ValuTrove® Neurostimulation Electrodes
510(k) Number	K#	K130987
Manufacturer	Philips Consumer Lifestyle	Axelgaard
Regulation Number	882.1320	882.1320
Product Code	GXY	GXY
Indication of use	The Philips Self-Adhesive Electrodes are intended for use with the PulseRelief device for applying Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscle Stimulation (EMS).	ValuTrove®) reusable, self-adhering, over-the-counter Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device

<p>Technology</p>	<p>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a printed silver pattern; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient's skin</p> <p>Axelgaard manufactures both the Philips Self-Adhesive Electrodes and the predicate electrodes K130987, with the same conductive hydrogel (tested for biocompatibility), conductive carbon film, printed silver pattern and electrode carrier liner.</p>	<p>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a printed silver pattern; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient's skin</p> <p>Axelgaard manufactures both the Philips Self-Adhesive Electrodes and the predicate electrodes K130987, with the same conductive hydrogel (tested for biocompatibility), conductive carbon film, printed silver pattern and electrode carrier liner.</p>
<p>Safety and effectiveness</p> <p>The average power density shall not exceed 0.25 watts per square centimeter of electrode conductive surface area.</p>	<p>Based on the successful biocompatibility testing of the skin contacting surface, the Philips Self-Adhesive Electrodes are safe and effective when used as an interface between a user's skin and the Philips PulseRelief device</p> <p>The maximum current of the device is 60mA. The device is current-controlled, so the current does not depend on the load. The maximum voltage is 60V. The size of the electrodes is 50mmx50mm with an equal current distribution.</p> <p>The pulse shape is rectangular, so the r.m.s. current is identical to the average current. The worst case r.m.s. current is in program 1, with two phases of 90µs at a repetition rate of 100Hz (10ms repetition duration), this results in average</p>	<p>Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the insulated lead wire components and electrode current distribution tests results, the Value Trode neuro stimulation devices are safe and effective when used as an interface between a user's skin and an approved neuro stimulation devices</p> <p>The axelgaard electrode will be used with different TENS devices, which is not the case for the Philips Self-Adhesive electrode that is only to be used with the PulseRelief and thus guarantee the power density of maximum of 0.0026 W/cm² which is below the maximum value.</p>

	current of $(2 \times 90 \mu\text{s} / 10 \text{ms}) \times 60 \text{mA} = 1.08 \text{mA}$. The surface of the electrodes is $50 \times 50 \text{mm} = 25 \text{cm}^2$. The current density is $1.08 \text{mA} / 25 \text{cm}^2 = 43 \mu\text{A r.m.s.}$ The power is the product of the current and the voltage, so the average power is $43 \mu\text{A} \times 60 \text{V} = 0.0026 \text{W/cm}^2$.	
Features/material	The electrode is composed of: <ul style="list-style-type: none"> • Top cover material; • Connection button ; • Conductive carbon film; • Conductive hydrogel; • Electrode carrier liner. 	The electrode is composed of: <ul style="list-style-type: none"> • Top cover material; • Connector lead wire or snap; • Conductive carbon film; • Conductive hydrogel; • Electrode carrier liner.
Size	5 x 5 cm ² (2in x 2in)	Several size including the same 5x5 cm ² (2in x2in)
Principles of Operation	Philips Self-Adhesive electrode are intended for use with TENS units as OTC devices. Some common type of neuro stimulation devices include, but are not limited to, TENS and EMS devices. TENS electrodes are passive devices serving as an interface between a user's skin and a neuro stimulation device	Value Trodes are intended for use with TENS units as OTC devices. Some common type of neuro stimulation devices include, but are not limited to, TENS and EMS devices. TENS electrodes are passive devices serving as an interface between a user's skin and a neuro stimulation device
Differences	Philips electrode has a metal button that enables a magnetic clamping with the Pulse Relief device	The ValueTrodes uses either snap or lead wires to connect with the TENS.

7. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination:

7.1 Biocompatibility testing

The biocompatibility evaluation for the Philips Self-Adhesive Electrodes device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. As dictated by the application and duration of contact with the intact skin, the battery of testing included the following tests:

- Cytotoxicity

- Sensitization
- Irritation

7.2 Other Performance Tests

The Philips Self-Adhesive Electrode is the same as the predicate device, the ValuTrode® Neurostimulation Electrodes from Axelgaard and it is manufactured by Axelgaard. Therefore the tests performed in the Neurostimulation Electrodes applies to the Philips Self-Adhesive Electrode.

1. Electrical & Impedance Tests

The Philips Self-Adhesive Electrode was tested to assure the current is equally distributed.

The Philips Self-Adhesive Electrode was also tested for Impedance to assure proper electrical connection to the skin.

2. Adhesion tests

The Philips Self-Adhesive Electrode was tested for initial adhesion force and adhesion force after using multiple times.

3. Connector & Mechanical tests

The TENS PulseRelief has a magnetic surface with the purpose to clamp the Philips Self-Adhesive Electrode. This connection was tested to assure multiple use and also to assure the TENS PulseRelief stay fixed to the Philips Self-Adhesive Electrode during use.

4. Packaging tests

The Philips Self-Adhesive Electrode was tested for storage conditions:

- The Philips Self-Adhesive Electrode should not be stored at temperatures lower than 41°F (+5°C) or higher than 80.6°F (+27°C).

5. Accelerated Aging

The Philips Self-Adhesive Electrode was tested for accelerate aging in worst storage condition to assure within the expiration date the electrode function as expected.

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8. CONCLUSION

The performance testing presented above establishes that the device is safe and effective for its intended use. The comparison tabulated above demonstrates that the device is substantially equivalent to the predicate devices.

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